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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,102	DADD ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31* is/are allowed.

6)☒ Claim(s) *1-10,13-18 and 20-29* is/are rejected.

7)☒ Claim(s) *11,12,19 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's amendment, which was received by the Office on October 31, 2005. No Claims have been cancelled. Claims 1-31 are active.

Claim Objections

2. Claims 2 and 31 are objected to because of the following informalities: there appears to be typographical errors in each claim. Specifically, in the first line of Claim 2, the Examiner suggests changing "cocklear" to "cochlear" to eliminate a spelling error. Specifically, in the tenth line of Claim 31, the Examiner suggests changing "suffer" to "stiffer" to eliminate a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 6-8 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neill (U.S. 4,154,247). As to Claim 1, O'Neill discloses an implantable tissue-stimulating device 10, comprising a resiliently flexible elongate member (see O'Neill column 3, lines 58-65 and column 4, lines 49-58) having a plurality of electrodes 12, 15 mounted thereon and having a first configuration (i.e. a linear configuration) selected to allow the member to be inserted into an implantee's body, a second configuration (i.e. a split curved configuration) wherein the elongate member is adapted to apply a preselected tissue stimulation with the electrodes 12, 15 (i.e. electrode 12 stimulates a ventricle and electrode 15 stimulates an atrium) (see O'Neill Figs. 1 and 4F, column 3, lines 9-21, column 4, lines 7-17 and column 7, lines 12-26). O'Neill further discloses that the device 10 also comprises a pair of first and second flexible electrical conductors 16 and 17 that each have an open passageway or lumen 19 disposed axially therealong to permit a stylet or stiff wire to be threaded into the lead 10 to provide the lead 10 with stiffness and maneuverability, enabling its insertion into a patient's heart during an operating procedure (see O'Neill Fig. 2 and column 4, lines 31-38).

In reference to the embodiment depicted in O'Neill Fig. 4F, a first stiffening stylet, read as a first stiffening element, is inserted into the lumen 19 of conductor 16 and a second stiffening stylet, read as a second stiffening element, is inserted into the lumen 19 of conductor 17 where both the first stiffening element and the second stiffening element, in combination, bias the elongate member of the lead 610 into a first linear configuration to allow the member to be inserted into an implantee's body (see O'Neill column 7, lines 12-23). The Examiner takes the position that due to the configuration of the lead 10 shown in O'Neill Fig. 1 and the corresponding configuration of the lead 610 shown in O'Neill Fig. 4F, second conductor 17 is

located in the portion of the lead 610 where electrode 612 is located and the first conductor 16 is located in the portion of the lead 610 where electrode 615 is located. The Examiner therefore also takes the position that when only one of the stiffening elements is removed from either one of the lumens of conductors 16, 17 the elongate member adopts only one half of the split configuration, read as an intermediate configuration between a first linear configuration and a second fully split configuration (see O'Neill column 7, lines 20-26). Furthermore, O'Neill disclose that an object of the invention is to provide a lead that is capable of being formed into a variety of configurations by the attending surgeon in order to adapt the lead to a particular patient (see O'Neill column 2, lines 39-42 and lines 50-52).

6. As to Claim 3, O'Neill discloses that the second configuration is a split curved configuration where the elongate member is adapted to apply a preselected tissue stimulation with the electrodes 12, 15 (i.e. electrode 12 stimulates a ventricle and electrode 15 stimulates an atrium) (see O'Neill Fig. 4F and column 7, lines 12-26).

7. As to Claim 6, in reference to O'Neill Fig. 5, O'Neill discloses that the implantable tissue-stimulating device 10 has a first end (specifically the bottom of the device 10) including a distal electrode 712 that is firstly inserted into the implantee and extends forwardly from the elongate member of the implantable tissue-stimulating device 10 (see O'Neill Fig. 5).

8. As to Claim 7, O'Neill discloses that the first configuration is asubstantially straight linear configuration selected to allow the member to be inserted into an implantee's body (see O'Neill column 3, lines 15-21 and column 7, lines 19-26).

9. As to Claim 8, O'Neill discloses that the implantable tissue-stimulating device 10 includes an first insulating layer 21 disposed about each conductor 16 and 17 axially along the

length of device 10 made of a heat-deformable material, e.g. a polypropylene, polyethylene, polyurethane or other thermally-deformable materials (see O'Neill column 3, lines 1-5 and 66-67 and column 4, lines 1-3).

10. As to Claim 27, O'Neill discloses that at least a portion of an outer surface of the elongate member of the implantable tissue-stimulating device 10 has a coating 21 of medical grade silicone rubber (see O'Neill column 3, lines 3-6 and column 4, lines 51-53). The Examiner takes the position that a surface made of silicone is synonymous with surface coated with a lubricious material because silicone is inherently a non-stick hydrophobic lubricous material.

11. Claims 1-4, 6-10, 15-18 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Treaba et al. (U.S. 6,421,569) (herein Treaba)

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

12. As to Claims 1-2 and 21, Treaba discloses a cochlear implant electrode array, read as a cochlear implant electrode assembly device 10 (see Treaba Abstract and Fig. 1a) comprising an elongate electrode carrier member 12 having a plurality of electrodes 32 (see Treaba Figs. 2a-2b, column 2, lines 50-52, column 4, lines 1-2 and lines 19-21) having a first, relatively straight configuration selected to allow the member 12 to be inserted into an implantee's cochlea and a

second, curved configuration to conform to the cochlea of a patient (see Treaba column 2, lines 35-65). The elongate electrode carrier member 12 of Treaba is made from a plastic material, such as medical grade silicone rubber, which is inherently a resiliently flexible first material (see Treaba Abstract, and column 4, lines 4-6).

Treaba further discloses that lumen 30 of the elongate member 12 may receive first and second stiffening stylets, read as first and second stiffening elements 44-1 and 44-2 (see Treaba column 8, lines 53-56), which in combination bias the pre-curved electrode assembly device 10 into the first, relatively straight configuration and then upon removal of either styles 44 from the elongate member 12, the array assumes a second curved configuration (see Treaba Figs. 7a-7d and 8a and 8b, column 2, lines 57-64, column 3, lines 14-22 and column 7, lines 36-39 and lines 65-67). Treaba discloses that preferably, the stylet 44 is relatively stiff along its entire length except for its tip; the tip is annealed to render it more malleable then the rest of the stylet 44 to allow the array 10 to flex easily as it is being inserted (see Treaba column 2, lines 64-67). Treaba further discloses that the second stiffening element 44-2 may only extend partially along the length of device 10, i.e. may be shorter than the first stiffening element 44-1 (see Treaba column 8, lines 55-56).

The Examiner takes the position that removal of the shorter stiffening element 44-2 will not cause the entire elongate carrier member 12 to fully adopt to the second fully curved configuration that occurs with complete removal of the longer stiffening element 44-1 (see Treaba column 8, lines 4-6). The Examiner also takes the position that the elongate carrier does not instantaneously or immediately change from a first straight configuration to a second fully curved configuration upon removal of stiffening elements 44 and it is inherent that the elongate

member 12 assumes an intermediate partially curved configuration between the first and second configurations, especially when a shorter second stiffening element 44-2 is used and removed first.

13. As to Claim 3, Treaba discloses that the elongate electrode carrier member 12 adopts a second configuration, which is curved, to conform to the cochlea of a patient (see Treaba column 2, lines 61-64).

14. As to Claim 4, Treaba discloses that the elongate electrode carrier member 12, when in the second curved configuration, adopts a spiral configuration 16 (see Treaba Fig. 1b and column 3, lines 65-67).

15. As to Claim 5, Treaba discloses that the elongate member 12 is preformed to the second, curved configuration and made of a plastic material such as medical grade silicone rubber (see Treaba column 4, lines 4-6). It is inherent that the plastic material that comprises the elongate member 12 also comprises memory capabilities because a straightening jig is necessary to insert the stiffening elements 44 which hold the member 12 straight and when the stiffening elements 44 are removed the elongate member re-assumes the pre-curved configuration (see Treaba column 3, lines 14-22 and Figs. 7a-7d).

16. As to Claim 6, Treaba discloses that the elongate electrode carrier member 12 has a first distal end or tip 10a that is firstly inserted into the implantee and that extends forwardly from the first end of the elongate member 12 (see Treaba Figs. 2a and 7a-7d and column 7, lines 24-27).

17. As to Claim 7, Treaba discloses that the elongate electrode carrier member 12 has a first, relatively straight configuration, selected to allow the member 12 to be inserted into an implantee's cochlea (see Treaba column 2, lines 59-61).

18. As to Claim 8, the elongate electrode carrier member 12 of Treaba is made from a plastic material, such as medical grade silicone rubber, which is inherently biocompatible (see Treaba Abstract, and column 4, lines 4-6).

19. As to Claims 9 and 15-17, Treaba discloses that the stiffening elements 44-1 and 44-2 are made from non-bioresorbable platinum stylet (see Treaba column 6, lines 8-15 and column 9, lines 30-34).

20. As to Claim 10, Treaba discloses that the stylet 44 is stiffer and more rigid than the first material of the carrier 12 (see Treaba column 3, lines 19-22).

21. As to Claim 18, Treaba further discloses that a single lumen 30 of the elongate member 12 may receive first and second stiffening stylets, read as first and second stiffening elements 44-1 and 44-2 (see Treaba column 8, lines 53-56).

22. As to Claim 29, it is inherent from the entire distal portion of elongate carrier 12's ability to assume a gradual increase in curvature (see Treaba Figs. 7a-7d) that the distal end or tip 10a is flexible.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 13-14, 22-25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treaba in view of Parker et al. (U.S. 5,653,742). As to Claims 13-14 and 22-23, Treaba

discloses the claimed invention as discussed above except that neither stiffening elements 44-1 or 44-2 are disclosed expressly to be formed of a bioresorbable material, which dissolves or softens upon exposure to body fluid, selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

Parker, however, discloses cochlear electrode array, read as an implantable tissue-stimulating device 20 comprising an elongate carrier member 12, made of a resiliently flexible elastic material, having a plurality of electrodes 16 mounted on the elongate carrier member 12. Parker also discloses that the device 20 comprises a stiffening element 18 that biases elongate member 12 into an insertion configuration, read as a first configuration allowing the member to be inserted into an implantee's body. Upon removal of the stiffening element 18 from the elongate member 12 the elongate member adopts a deployed configuration, read as a second curved configuration where the elongate member is adapted to apply preselected tissue stimulation with the electrodes 16 (see Parker Abstract, Figures 1 and 2, column 3, lines 30-35 and lines 53-67 and column 4, lines 1-4). Parker further discloses that the elongate member 12 is preformed from a plastics material with memory and is preformed to the second curved configuration (see Parker column 3, lines 23-30).

Parker further discloses that the stiffening element 18 is made of a bioresorbable material, which dissolves or softens up on insertion into a cochlea, and may be made of polyvinyl alcohol (PVA), polylactic acid (PLA), polyglycolic acid (PGA) and other similar compounds (see Parker Abstract, column 2, lines 35-37 and column 3, lines 38-41). Parker does not explicitly state why the bioresorbable material is used, but it appears that a bioresorbable-stiffening element is used to provide increasing flexibility of the elongate member the member is inserted into the body,

such as the cochlea. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the either stiffening element as taught by Treaba, with a bioresorbable-stiffening element made of polyvinyl alcohol (PVA), polylactic acid (PLA), polyglycolic acid (PGA) and other similar compounds, as taught by Parker, since such a modification would provide the device with a bioresorbable-stiffening element for providing increasing flexibility of the elongate member upon insertion of the member into the cochlea.

25. As to Claims 24 and 25, Treaba discloses the claimed invention as discussed above except that the device does not include an additional layer surrounding the elongate member, the additional layer having a first rate of fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer and wherein the fluid ingress means comprises one or mare slits in the additional layer.

Parker, however, discloses cochlear electrode array, read as an implantable tissue-stimulating device 20 comprising an elongate carrier member 12, made of a resiliently flexible elastic material, having a plurality of electrodes 16 mounted on the elongate carrier member 12. Parker also discloses that the device 20 comprises a stiffening element 18 that biases elongate member 12 into an insertion configuration, read as a first configuration allowing the member to be inserted into an implantee's body. Upon removal of the stiffening element 18 from the elongate member 12 the elongate member adopts a deployed configuration, read as a second curved configuration where the elongate member is adapted to apply preselected tissue stimulation with the electrodes 16 (see Parker Abstract, Figures 1 and 2, column 3, lines 30-35 and lines 53-67 and column 4, lines 1-4). Parker further discloses that the elongate member 12 is

preformed from a plastics material with memory and is preformed to the second curved configuration (see Parker column 3, lines 23-30).

Parker further discloses in Fig. 5 an alternate embodiment of the device comprising an additional layer which has a first rate of fluid ingress therethrough and has at least one fluid ingress means formed therein 19', the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer. The fluid ingress means comprises one or more dimples, read as slits 17' in the additional layer of the elongated member 12. Parker also discloses that the purpose of the slits is to hold a stiffener material 19'. The stiffener 19' material of Parker is introduced into the slits 17' only after the carrier 10' is deformed to assume a straight or linear configuration, as seen in FIG. 5. The material is the same material as the material of sheath 18, that is, it is bioresorbable. In the embodiment of FIG. 5, the material 19' provides rigidity to the carrier 10' to prevent the carrier 10' from taking its spiral shape. In this manner, the carrier 10' can be readily implanted into the scala tympani. After implantation, the material 19' dissolves in the cochlear fluid and allows the carrier 10' to move back to its spiral shape (see Parker Fig. 5 and column 4, lines 5-21).

It would have been obvious to on having ordinary skill in the art at the time the invention was made to modify the device of Treaba in view of Parker to include an additional layer surrounding the elongate member, the additional layer having a first rate of fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer and wherein the fluid ingress means comprises one or mare slits in the additional

layer to further hold the elongate member in a relatively straight configuration so that it may be implanted into the scala tympani.

26. As to Claim 27, Treaba discloses the claimed invention as discussed above except that at least a portion of the outer surface of the elongate member is disclosed to be coated with a lubricious material.

Parker, however, discloses cochlear electrode array, read as an implantable tissue-stimulating device 20 comprising an elongate carrier member 12, made of a resiliently flexible elastic material, having a plurality of electrodes 16 mounted on the elongate carrier member 12. Parker also discloses that the device 20 comprises a stiffening element 18 that biases elongate member 12 into an insertion configuration, read as a first configuration allowing the member to be inserted into an implantee's body. Upon removal of the stiffening element 18 from the elongate member 12 the elongate member adopts a deployed configuration, read as a second curved configuration where the elongate member is adapted to apply preselected tissue stimulation with the electrodes 16 (see Parker Abstract, Figures 1 and 2, column 3, lines 30-35 and lines 53-67 and column 4, lines 1-4). Parker further discloses that the elongate member 12 is preformed from a plastics material with memory and is preformed to the second curved configuration (see Parker column 3, lines 23-30).

Parker further discloses an implantable tissue-stimulating device wherein at least a portion of an outer surface of the elongate member 12, surrounded by stiffening element 18, has a coating of a lubricious material to reduce friction and also may be made of a time-released antimicrobial material to provide protection against infections during implantation (see Parker column 3, lines 40-48). Therefore it would have been obvious to one having ordinary skill in the

art at the time the invention was made to modify the elongate member of Treaba in view of Parker to be coated with a lubricious material to reduce provide protection against infections during implantation.

27. As to Claim 28, the previously modified Treaba reference discloses the claimed invention as discussed above except the lubricous material is not disclosed to be selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to select the lubricous material from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

28. Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Treaba in view of Kuzma (U.S. 6,119,044). As to Claim 20, Treaba discloses the claimed invention as discussed above except that neither the first 44-1 or second 44-2 stiffening elements are disclosed as being formed from a shape memory material.

Kuzma, however, discloses an implantable electrode array 10 including a flexible carrier body 13 having a channel 11 (see Kuzma column 7, lines 16-20) for receiving a positioning stylet 20 made from a memory wire that assumes a relatively straight, or non-spiral shape for insertion purposes and curves to fit the cochlea wall after insertion (see Kuzma column 7, lines 35-50). The memory wire assumes or returns to the desired curvature needed to place the electrodes of the array against the modiolar wall so that the curvature wraps as snugly as possible

around the modiolus of the cochlea in order to make the best electrode contact with the implantee (see Kuzma column 3, lines 35-40 and lines 60-64 and column 4, lines 21-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify either stiffening element of Treaba in view of Kuzma with shape memory stiffening stylet in order to facilitate bending of the array with the electrodes on the inside of the bend to place the electrodes of the array against the modiolar wall so that the curvature wraps as snugly as possible around the modiolus of the cochlea in order to make the best electrode contact with the implantee.

29. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Treaba in view of Parker and Kuzma. Treaba discloses the claimed invention as discussed above except that neither the first 44-1 or second 44-2 stiffening elements are disclosed as being formed from a bioresorbable material, which dissolves or softens upon exposure to body fluid.

Parker, however, discloses cochlear electrode array, read as an implantable tissue-stimulating device 20 comprising an elongate carrier member 12, made of a resiliently flexible elastic material, having a plurality of electrodes 16 mounted on the elongate carrier member 12. Parker also discloses that the device 20 comprises a stiffening element 18 that biases elongate member 12 into an insertion configuration, read as a first configuration allowing the member to be inserted into an implantee's body. Upon removal of the stiffening element 18 from the elongate member 12 the elongate member adopts a deployed configuration, read as a second curved configuration where the elongate member is adapted to apply preselected tissue stimulation with the electrodes 16 (see Parker Abstract, Figures 1 and 2, column 3, lines 30-35 and lines 53-67 and column 4, lines 1-4). Parker further discloses that the elongate member 12 is

preformed from a plastics material with memory and is preformed to the second curved configuration (see Parker column 3, lines 23-30).

Parker further discloses that the stiffening element 18 is made of a bioresorbable material, which dissolves or softens up on insertion into a cochlea, and may be made of polyvinyl alcohol (PVA), polylactic acid (PLA), polyglycolic acid (PGA) and other similar compounds (see Parker Abstract, column 2, lines 35-37 and column 3, lines 38-41). Parker does not explicitly state why the bioresorbable material is used, but it appears that a bioresorbable-stiffening element is used to provide increasing flexibility of the elongate member the member is inserted into the body, such as the cochlea. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the either stiffening element as taught by Treaba, with a bioresorbable-stiffening element made of polyvinyl alcohol (PVA), polylactic acid (PLA), polyglycolic acid (PGA) and other similar compounds, as taught by Parker, since such a modification would provide the device with a bioresorbable-stiffening element for providing increasing flexibility of the elongate member upon insertion of the member into the cochlea.

The previously modified Treaba reference discloses the claimed invention as discussed above except that neither the first 44-1 or second 44-2 stiffening elements are disclosed as being formed from a shape memory material. Kuzma, however, discloses an implantable electrode array 10 including a flexible carrier body 13 having a channel 11 (see Kuzma column 7, lines 16-20) for receiving a positioning stylet 20 made from a memory wire that assumes a relatively straight, or non-spiral shape for insertion purposes and curves to fit the cochlea wall after insertion (see Kuzma column 7, lines 35-50). The memory wire assumes or returns to the desired curvature needed to place the electrodes of the array against the modiolar wall so that the

curvature wraps as snugly as possible around the modiolus of the cochlea in order to make the best electrode contact with the implantee (see Kuzma column 3, lines 35-40 and lines 60-64 and column 4, lines 21-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify either stiffening element of Treaba in view of Kuzma with shape memory stiffening stylet in order to facilitate bending of the array with the electrodes on the inside of the bend to place the electrodes of the array against the modiolar wall so that the curvature wraps as snugly as possible around the modiolus of the cochlea in order to make the best electrode contact with the implantee.

Allowable Subject Matter

30. Claims 11-12, 19 and 30 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

31. Claim 31 is allowed.

32. The following is a statement of reasons for the indication of allowable subject matter:

The claims in Application #10/070,102 are deemed to be directed to a non-obvious improvement over the prior art. Treaba discloses a cochlear implant electrode array, read as a cochlear implant electrode assembly device 10 (see Treaba Abstract and Fig. 1a) comprising an elongate electrode carrier member 12 having a plurality of electrodes 32 (see Treaba Figs. 2a-2b, column 2, lines 50-52, column 4, lines 1-2 and lines 19-21) having a first, relatively straight configuration selected to allow the member 12 to be inserted into an implantee's cochlea and a second, curved configuration to conform to the cochlea of a patient (see Treaba column 2, lines

35-65) as discussed above in this Office Action. Treaba, does not disclose a first stiffening element made of a material relatively stiffer than the material of the electrode array and a second stiffening element stiffer than the first stiffening element and with a larger diameter than the first stiffening element. Treaba also does not disclose that either stylet comprises a lumen for accepting the other stylet. The prior art made of record also fails to provide a choclear electrode array, synonymous with Treaba that comprises a flexible tip member comprising metallic particles dispersed throughout to control the depth of flexibility of the tip member.

The references of the prior art fail to show or teach all of the Applicant's claimed invention and fail to show or teach any obvious type improvement over Treaba and as a result, the Examiner deems these claims to be allowable over the prior art.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel
Examiner
Art Unit 3766

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